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14. ABSTRACT

This study consists of a comparative effectiveness trial of Transcendental Meditation (TM) compared to Prolonged Exposure (PE) and education control (EC) groups in Veterans diagnosed with clinically significant PTSD by way of a validated structured interview methodology over a treatment period of three months. Two hundred and ten veterans will participate in this three-arm trial. Testing will be conducted at 0 and 3 months for PTSD symptoms, psychological distress, depression, quality of life, behavioral factors, and physiological/ biochemical mechanisms using validated interview, self-report, and biological measures. Recruitment began in June of 2013. We hypothesize that TM will be non-inferior to PE on the primary outcome of the study and superior to EC on PTSD study outcomes. This will be a multidisciplinary, collaborative research project comprising investigators from the San Diego VA Healthcare System, the University of California at San Diego and Maharishi University of Management Research Institute. Given a sample of 210 patients, an alpha level of .05 for declaring statistical significance, equal standard deviations, and an attrition rate of 20%, estimated power levels are ≥.90.

15. SUBJECT TERMS
PTSD, transcendental meditation, exposure therapy, clinical trial

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A Randomized, Controlled Trial of Meditation Compared to Exposure Therapy and Education Control on PTSD in Veterans
Partnering PI: Dr. Thomas Rutledge

Year 1 Annual Technical Report. August, 2013.

INTRODUCTION: Posttraumatic stress disorder (PTSD) is a common and disabling condition among Veterans, with few efficacious treatments available. The purpose of this clinical trial is to: 1) To evaluate effects of Transcendental Meditation (TM) vs. Prolonged Exposure (PE) and education control (EC) controls on PTSD; and 2) To evaluate effects of TM vs. PE and EC on PTSD symptoms, depression, anger, quality of life, and physiological/biochemical stress markers. Prior evidence supports TM as a treatment for anxiety and stress symptoms; however, the efficacy of TM as a standalone treatment for psychiatric anxiety disorders is unknown at this time.

BODY: Task 1: Final DoD ORP approval was given for our staff to begin recruitment on May 31, 2013. This approval came after we made several human subjects-related adjustments based upon DoD ORP requests. The most significant of these requests involved receiving approval from the VASDHS IRB to do consenting over the phone prior to conducting initial phone screens.

Task 2: Hiring and Training of Staff. We completed the hiring of our three full-time staff coordinators and a 50% time Prolonged Exposure study therapist, consistent with the hiring plan proposed in our research proposal.

Task 3: We completed our Case Report Forms and Operations Manuals during this period and did some minor edits. Study statistician, Dr. Rainforth, completed the MS Access database for data entry personnel at VASDHS. Piloting of this database took place. Dr. Rainforth and the data manager oversee the data entry and database management process and consult weekly.

Task 4 thru 9 – We began recruitment, screening of subjects, baseline testing, and randomization of subjects on June 3, 2013. The staff is taking a number of effective angles on recruitment, including the posting of flyers at the VA, giving presentations to community Veterans groups, placing information in VA and Veterans newsletters, and presenting the study to nurses and health-care providers at the VASDHS for referrals. An Internet website for recruitment is also being finalized. We have also purchased advertisement space in local San Diego newspapers that contain sections targeting military populations and potential research participant populations.

During the past few weeks since approval to begin the study: we have had 77 phone inquiries, 57 phone screens, 31 eligible for the study and consented, 25 completing baseline visit one, 14 completing baseline visit two, and 14 randomized. Study recruitment appears to be occurring consisting with our projected timeline. All three treatment arms are operational.

Task 10: Overall Project Management has been progressing smoothly. The PI, Dr. Nidich at MUMRI and partnering PI, Dr. Rutledge at VASDHS, San Diego have engaged in weekly teleconference calls with study investigators, hired staff, and treatment providers, to discuss start-up phase tasks, recruitment, testing of subjects, randomization, and treatment delivery.

These conference calls will be ongoing throughout the trial. Additional communication between PI's and investigators takes place throughout the week as needed.

KEY RESEARCH ACCOMPLISHMENTS:

- Study recruitment began on June 3, 2013 following DOD ORP approval.
- We have completed all study hires, with all treatment therapists institutionally approved at the VA San Diego Healthcare System, and active in treatment delivery.
- As of August 26, 2013, we have randomized 14 participants in seven full weeks of recruitment, a pace slightly ahead of our proposed recruitment timeline in the research plan.
- We assembled a four-member DSMB panel to oversee our study, with the panel meeting on July 18 to review our study protocol. The DSMB will meet again in November/December for a six-month study review. The DSMB membership includes Dr. Charles Elder, the study medical monitor, is chair of the DSMB, two clinical psychologists who are active researchers and faculty in the UC San Diego Department of Psychiatry, and a biostatistician with the Department of Family and Preventive Medicine from UC San Diego.
- A member of our research team attended the 2013 Military Health Research Forum in Florida.

REPORTABLE OUTCOMES: Not applicable. With our study eight weeks into recruitment, we do not yet have publications, abstracts, or other awards to report.

CONCLUSION:

This report summarizes study progress over the initial twelve months of funding approval. The majority of this interval (ten months) involved obtaining institutional review board approvals (VA San Diego Healthcare System, Maharishi Institute of Management, DOD ORP), hiring staff, forming a DSMB panel, and initiating recruitment in June of 2013. Based upon the previous two months of recruitment, we are randomizing participants to recruitment at a rate consistent with projections and have experienced no significant problems or adverse events.

Implications

Although both cognitive behavioral and pharmacological strategies are effective in the treatment of some Veterans with PTSD, approximately half of patients maintain clinically significant impairment despite treatment. The latter circumstance suggests a need for additional treatment options for this Veteran population. The proposed study attempts to evaluate a standardized meditation treatment for PTSD disorder. The short-term aim of this proposal is to evaluate a novel treatment for PTSD in comparison to existing treatments commonly available to Veterans. Based upon preliminary research, we have reason to expect clinically significant reductions in PTSD symptoms among TM participants. Equally important, however, are the longer-term prospects, which include the possibility of augmenting current PTSD therapies in the VA with an easily importable, patient-friendly, and low or no side effect treatment modality with known benefits for multiple areas of quality of life.

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APPENDICES: Not applicable.

SUPPORTING DATA:

Figure 1. Recruitment progress table, June, 2013-Present (unpublished data).

weekly date /Cumulative	# calls	# phone screened	completed BLT (visit 1)	Completed BLT (visit 2)	Randomized
DATE: 6/10/13-6/14/13	9	8	2	0	0
Cumulative 1	9	8	2	0	0
DATE: 6/17/13-6/21/13	8	7	5	2	0
Cumulative 2	17	15	7	2	0
DATE: 6/24/13-6/28/2013	7	5	4	3	3
Cumulative 3	24	20	11	5	3
DATE: 7/1/2013- 7/5/2013	5	2	1	3	4
Cumulative 4	29	22	12	8	7
DATE: 7/8/2013-7/12/2013	7	2	1	0	1
Cumulative 5	36	24	13	8	8
DATE: 7/15/2013-7/19/2013	8	5	0	0	0
Cumulative 6	44	29	13	8	8
DATE: 7/22/2013 - 7/26/2013	4	3	3	1	1
Cumulative 7	48	32	16	9	9
DATE: 7/29/2013-8/2/2013	11	7	1	2	1
Cumulative 8	59	39	17	11	10
DATE: 8/5/2013-8/9/2013	9	9	4	1	2
Cumulative 9	68	48	21	12	12
DATE: 8/12/2013-8/16/2013	5	7	2	0	0
Cumulative 10	73	55	23	12	12
DATE: 8/19/2013-8/23/2013	4	3	2	2	2
Cumulative 11	77	58	25	14	14